# EXHIBIT W

**Risk assessment TVT blue**

No changes have been made to the product and its intended use, apart from the colour. The biocompatibility of this new variations has been evaluated (section 9) and it has been concluded that the product will have the same safety level as the existing product.

Also the clinical evaluation revealed no new risks (section 11)

The design validation shows that the new variation delivers the intended visibility.

As no new risks have been identified the original risk assessment for TVT clear is also valid for TVT blue.

J. Jofer 29.05.02

**Anhang 4-02/3:** Bewertung der Gefahrenarten (Risikoanalyse nach EN 1441)

**Product: TVT** **Projekt :** ***Design Review:*** X ***Prozeß FMEA:***

**Prozeßschritt:**

| Hazard | Source | Exposition / potential consequence | Failure Mode | Probability of occurance | Risk Class | Applicable safety measure | Other hazards generated? | Risk Class | Assessment of remaining risk |
|---|---|---|---|---|---|---|---|---|---|
| 1) Bioburden | Manufacturer | Longterm/ Serious | Failure | Rare | 5 | Manufacturing under GMP-conditions, Control of bioburden | No | 1 | negligible |
| 2) Non-decomposable residues | Manufacturer | Longterm/ Serious | Failure | Rare | 5 | Washing of needle, Biocompatibility-testing | No | 1 | negligible |
| 3) Pyrogenity | See 1 | | | | | | | | |
| 4) Wrong composition of material | See 19g and h | | | | | | | | |
| 5) Systemic Toxicity | Manufacturer | Longterm / Serious | Failure | Rare | 5 | Biocompatibility-testing | No | 1 | negligible |
| 6) Genotoxicity /Teratogenicity | See5 | | | | | | | | |
| 7) Allergical Effects | See5 | | | | | | | | |
| 8) Cytotoxicity | See5 | | | | | | | | |
| 9) Other bio-incompatibilities | n.a. | | | | | | | | |
| 10) Non-obedience of hygiene | User | Long / Serious | Failure | occasional | 6 | No special measures, as risk is not product specific | | | |
| 11) (Cross-)Infection | n.a. | | | | | | | | |
| 12) Incompatibility with other devices or products | Use of former introducer version | Short / marginal | Failure | Frequent | 1 | Old version was retrieved from the customer. Customer information | No | 0 | acceptable |
| 13) Lack of qualitative properties | | | | | | | | | |
| Treatment is not successfull | Not known | Long/ critical | Standard use | Probable | 6 | Patient-consent, less invasive than standard procedures | No | 3 | Risk accepted by patient |
| a) functional and qualitative properties | | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| a.a) no sufficient friction to maintain position even under stress without fixation | Manufacturer (wrong product / process) | Long / critical | Failure | Probable | 5 | Inspections at receiving, manufacturing and release of material / product | No | 0 | acceptable |
| | User ( user does not remove the sheath) | Long / Critical | Failure | Probable | 5 | Package insert and training of users | No | 0 | acceptable |
| 13.a.b) Complication rate higher than standard procedures | See 28 clinical risks | | | | | | | | |
| 13.a.c) Procedure cannot be performed under local or regional anesthesia (no cough-test possible) | Surgeon / patient | Long / Critical | Standard use | Rare | 4 | Cough-test required in package insert | No | I | negligible |
| 13.a.d) No shorter recovery time | Conversion to open surgery | Long / critical | Standard use | Frequent | 6 | Patient-consent | No | 3 | Risk accepted by patient |
| 13.a.e) Open surgery required | See 13.a.d) | | | | | | | | |
| 13a.f) Operating time higher than for standard procedure | Surgeon | Short / marginal | Standard use | Rare | 0 | | | 0 | acceptable |
| 13.a.g) Needle curvature is not as required | Manufacturer | Short / serious | Failure | Occasional | 6 | Inspections at receiving, manufacturing and release of material / product | No | 0 | Acceptable |
| 13.a.h) Needle tip is not as required (too sharp) | Manufacturer | Short / serious | Failure | Rare | 5 | Radius is specified, qualitative inspection at receiving | No | 0 | Acceptable |
| Needle tip is not as required (not as sharp as required) | Manufacturer | Short / serious | Failure | Rare | 5 | Radius is specified, qualitative inspection at receiving | No | 0 | Acceptable |
| 13.a.i) Needle diameter is not as required | Not imaginable | | | | | | | | |
| 13.a.j) Needle end causes additional trauma | Not imaginable | | | | | | | | |
| 13.a.k) Needle too short | Manufacturer | Short / marginal | Failure | Remote | 0 | | No | 0 | Acceptable |

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|---|---|---|---|---|---|---|---|---|---|
| 13.a.l) Needle does not allow the attachment of the introducer | Manufacturer / User | Short / moderate | Failure | Rare | 1 | | No | 1 | Acceptable |
| 13.a.m) Sheath does not glide easily | Not imaginable | | | | | | | | |
| **13 b)** Treatment (not cuttable) | Not imaginable | | | | | | | | |
| **13 c)** Mesh will be fixated | Surgeon | No hazard | | | | | | | |
| **13 d)** Mix-up (cannot be ditinguished from other products) | Not imaginable | | | | | | | | |
| **13 e)** Not manageable with gloves | Not imaginable | | | | | | | | |
| **13 f)** Not manageable with instruments | Not imaginable | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| **14)** Human error/Reuse of disposable product | Not imaginable | | | | | | | | |
| **15)** Insufficient warning of adverse reactions (only product related) | See 28 Clinical risks | | | | | | | | |
| **16)** Loss of mechanical integrity | See 19 a and g | | | | | | | | |
| **17)** Erroneous mechanical damage | Surgeon | No hazards | | | | | | | |
| **18)** Contamination as a result of waste –product and/ or waste of equipment | No special product related hazard | | | | | | | | |
| **19)** Lack of quantitative properties | | | | | | | | | |
| **a)** Mechanical Properties a.a) needle | | | | | | | | | |
| a.a.a) Needle strength (needle breakage) | Manufacturer | Short / marginal | Failure | Frequent | 1 | | No | 1 | Negligible |
| a.a.b) Needle bending (elastic deformation) | No hazard | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| a.a.b) Needle bending (plastic deformation) | Surgeon | Short / marginal | Failure | Probable | 0 | | No | 0 | Acceptable |
| a.a.c) Internal thread strength | Manufacturer | Short / marginal | Failure | Probable | 0 | | No | 0 | Acceptable |
| a.a.d) Penetration resistance at urogenital diaphragma is too high | See 13 a.h | | | | | | | | |
| a.b.) Mesh | | | | | | | | | |
| a.b.a) tensile strength | Manufacturer | Short / marginal | Failure | Probable | 0 | | No | 0 | Acceptable |
| a.b.b) elongation | Manufacturer | Long / critical | Failure | Occasional | 4 | Inspection at receiving | No | 0 | Acceptable |
| a.b.c) bending stiffness | Manufacturer | Long / critical | Failure | Occasional | 4 | Inspection at receiving (Identity) | No | 0 | Acceptable |
| a.b.d) pore size | Manufacturer | Long / critical | Failure | Occasional | 4 | Inspection at receiving (Identity) | No | 0 | Acceptable |
| a.c) assembly | | | | | | | | | |
| a.c.a) push-off force | Manufacturer | Short / moderate | Failure | Frequent | 3 | Process validation according to defect class I | No | 0 | Acceptable |
| b) Dimesions | | | | | | | | | |
| b.a) needle | | | | | | | | | |
| b.a.a.(below min. diameter at shoulder) | Manufacturer | Short / critical | Failure | Remote | 2 | Inspection at receiving | No | 0 | Acceptable |
| b.b) mesh | | | | | | | | | |
| b.b.a) too short | Manufacturer | Short / moderate | Failure | Remote | 2 | Inspection during manufacturing | No | 0 | Acceptable |
| b.b.b ) too small | Manufacturer | Long / critical | Failure | Rare | 3 | Inspection during manufacturing | No | 0 | Acceptable |
| b.c) sheath (too short) | Manufacturer | Short / marginal | Failure | Probale | 0 | Inspection during manufacturing | No | 0 | Acceptaable |
| b.d) shrink tube | See 19.a.c.a | | | | | | | | |
| c) colour / appearence | | | | | | | | | |
| c.a) needle | Not imaginable | | | | | | | | |
| c.b) mesh | Not imaginable | | | | | | | | |
| c.c) sheath | See 19.a.c.a | | | | | | | | |
| c.d) shrink tube | Not imaginable | | | | | | | | |
| d) tightness | n.a. | | | | | | | | |
| e) strength of mesh (vivo / vitro) | Not imaginable | | | | | | | | |
| f) absorption | n.a | | | | | | | | |
| g) Composition | | | | | | | | | |
| g.a) needle | See 19.a.a.a | | | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|
| g.a.a (needle breakage) | See 19.a.a.a | | | | | | | | |
| g.a.b (biocompatibility) | Manufacturer | short / serious | Failure | Incredible | 2 | Inspection at receiving (Identity) | No | 0 | Acceptable |
| g.b) mesh | Not imaginable | | | | | | | | |
| g.c) sheath | See 19.b.c | | | | | | | | |
| g.d) shrink tube | See 19.a.c.a | | | | | | | | |
| **h.)** construction | | | | | | | | | |
| h.a) mesh | See 13.a.a | | | | | | | | |
| h.b) attachment | See19.a.c.a | | | | | | | | |
| h.c) transition | See 19.a.c.a | | | | | | | | |
| | | | | | | | | | |
| **20)** Missing adequate determination when the usability of the product expires | Not imaginable | | | | | | | | |
| **21)** Insufficient Packaging **a)** Contamination of the product or user | Manufacturer | Long / serious | Failure Mode | | | | | | |
| **b)** Decline of equipment/device condition | | | | | | | | | |
| **22)** Discharge of liquids | Not applicable | | | | | | | | |
| **23)** Magnetic Fields | Not applicable | | | | | | | | |
| **24)** Electrocauter | | | | | | | | | |
| **25)** Moisture Storage/Transport | | | | | | | | | |
| **26)** Air pressure Storage/Transport | | | | | | | | | |
| **27)** Temperature Storage/Transport | | | | | | | | | |
| **28)** Clinical Risks | | | | | | | | | |
| **a)** Intraoperative bladder perforation | User | Long / critical | Failure Mode | Probable | 5 | -Info in IFU (Diagnostic by Cystoscopy) and Training of User | No | 0 | acceptable |

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|---|---|---|---|---|---|---|---|---|---|
| **b)** Intraoperative blood loss exceeding 300 ml blood coagulation dissorder or injury of minor vessels) | User | long / moderate | Failure Mode | Rare | 4 | Patient monitoring is standard procedure | No | 0 | acceptable |
| **c)** Overtensioning of tape | User | Long / critical | Failure Mode | Probable | 5 | -Info in IFU<br>-Training | No | 0 | Acceptable |
| **d)** Level of wound infection and urinary tract infection higher than for other incontinence procedures | Not imaginable | | | | | | | | |
| **e)** Injury of major vessels | User | Short / serious | Failure Mode | Frequent | 7 | -Info in IFU<br>-Training<br>-Restricted marketing (only to customers , equiped to be able to treat the injury<br>- During the training it must be emphazized that the procedure should only be performed if a quick access to an intensive care unit is available | No | 1 | negligible |
| **f)** Injury of nerves | User | long / serious. | Failure Mode | Ocassional | 6 | -Info in IFU<br>-Training | No | 1 | negligible |
| **g)** Injury of bowel | User | Short / serious | Failure Mode | Occasional | 6 | -Info in IFU<br>-Training | No | 1 | Negligible |
| **h)** Injury of urethra | User | Short / critical | Failure Mode | Frequent | 3 | - Info in IFU<br>- Training | No | 0 | Acceptable |
| **i )** Bladder perforation | User | Short / critical | Failure Mode | Frequent | 3 | - Info in IFU<br>- Training | No | 0 | Acceptable |
| **j)** Prolonged urinary retention | See 28c | | | | | | | | |
| **k)** De novo detrusor instability | User | Long / critical | Failure Mode | Occasional | 4 | - Info in IFU<br>- Training | No | 0 | Acceptable |
| **l)** Postoperative erosion of urethra | User | Long / critical | Failure Mode | Occasional | 4 | - Info in IFU<br>- Training | No | 0 | Acceptable |

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|---|---|---|---|---|---|---|---|---|---|
| **m)** Postoperative erosion of bladder | Standard procedure | Long/ critical | Standard-use | Incredible | 2 | | No | 2 | Acceptable as clinically not observed |
| **n)** Postoperative erosion of vagina | Delayed healing caused by: Patient or surgeon | Long / moderate | Failure Mode | Occasional | 4 | Surgeon : Info in IFU Training | No | 0 | Acceptable as it is equivalent to standard procedures and not product specific |
| **o)** Haematoma which needs treatment (removal) | Procedure related | Long / critical | Standard use | Incredible | 2 | Patient-consent, less invasive than standard procedures | No | 2 | General risk for invasive procedures. Risk accepted by patient |
| ) Haematoma which needs treatment (removal) | Surgeon | Long / critical | Failure Mode | Improbable | 3 | Patient-consent, less invasive than standard procedures | No | 3 | General risk for invasive procedures. Risk accepted by patient |
| 29) Others | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

Is safety of product adequate ? Yes ☒ No ☐ Further measures:.....

Carried out by: J. Höfer Date: 08.05.01 Reviewed by: ..... Reg. Aff.

Scientific Director 8.5.01

Medical Affairs B. Hellmann / 8.5.01

Marketing Manger

Proj. L. Scient. Aff. C. Wecker / 14.05.01

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **m)** Postoperative erosion of bladder | Standard procedure | Long/ critical | Standard-use | Incredible | 2 | | No | 2 | Acceptable as clinically not observed |
| **n)** Postoperative erosion of vagina | Delayed healing caused by: Patient or surgeon | Long / moderate | Failure Mode | Occasional | 4 | Surgeon : Info in IFU Training | No | 0 | Acceptable as it is equivalent to standard procedures and not product specific |
| o) Haematoma which needs treatment (removal) | Procedure related | Long / critical | Standard use | Incredible | 2 | Patient-consent, less invasive than standard procedures | No | 2 | General risk for invasive procedures. Risk accepted by patient |
| ) Haematoma which needs treatment (removal) | Surgeon | Long / critical | Failure Mode | Improbable | 3 | Patient-consent, less invasive than standard procedures | No | 3 | General risk for invasive procedures. Risk accepted by patient |
| 29) Others | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

Is safety of product adequate ? Yes ☒ No ☐ Further measures:.....

Carried out by: T. Hofer..... Date: 08.05.01 Reviewed by:.....

Reg. Aff.

Scientific Director 8.5.01 Marketing Manger 31/05/01

Medical Affairs B. Hellmanns / 8.5.01 Proj. L. Scient. Aff. C. Lücke / 14.05.01

**ETHICON SARL**

# QA Memo

**To:** .Technical File

**From:** Agnès SIFFERLEN

**CC:**

**Date:** July 26, 2000

**Subject: RISK ANALYSIS**

**Re:** QAMemo1700

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The original risk analysis for TVT implant and introducer written by Medscan is still valid (see risk analysis rev 7 dated February 6, 2000).

An additional analysis was done to document the packaging change. (see Device design safety assement summary report rev 0)

Agnès SIFFERLEN

Quality System and compliance supervisor.

PREVENTIA

# TVT-2

| Product: | Artkel No: |
|---|---|
| TVT-2 needles, introducer | TVT-2 |
| Customer: | Responsible: |
| | ME / TS |
| Prepared: | Revision date: |
| 1998-09-22 | 2008-02-06 |
| Revision No: | |
| 7 | |
| Approved by: | |
| Preventia AB, Dep Education / 0256-1 | |

PREVENTIA

# TVT-2

| | | |
|---|---|---|
| Reg No: MED-91 Eng | Artikl No: TVT-2 | Product: TVT-2 needles, introducer |
| Note: Treatment of SUI | Drawing No: P15113, P15111, P15112 | Dept: QA |
| Customer: | Responsible: ME / TS | Prepared: 1998-09-22 |
| Revision No: 7 | Revision date: 2000-02-06 | Page: 1 of 1 |

## Note

Analysis made 1998-09-22 by Margareta Eriksson and Tommy Svensson (PREVENTIA AB).
System description, see attached drawings.

Review of analysis 1999-01-27 by Margareta Eriksson and Tommy Svensson (PREVENTIA AB).
The revised TVT-2 device:
5 mm needle
Shiny surface
Tip angle same as 6 mm
Transparent shrink tubo
Packed in double plastic
Handle screw instead of o-ring

Utgåva 4 1999-06-01
Genomgång av ME / TS

Utgåva 5 1999-06-23
Ny värdering av risker TS / ME

Issue 6
Review of risk analysis based surveillance data and complaint statistics 1999.
Performed by ME and TS 2000-02-02.

Issue 7
Revision ov text and Risknumbers after action taken (typing errors)

PREVENTIA

# TVT-2

| | | |
|---|---|---|
| Reg No: MED-91 Eng | Artikl No: TVT-2 | Product: TVT-2 needles, introducer |
| Note: Treatment of SUI | Drawing No: P15183, P15181, P15182 | Dept: QA |
| Customer: | Responsible: ME / TS | Prepared: 1998-09-22 |
| Revision No: 7 | Revision date: 2000-02-06 | Page: 1 of 1 |

## Scales

**RPN = Po*S *Pd**

**Po, Prob of occur.**
1 Not likely, <1:100 000
2 Very low probability, <1:50 000
3 Very low probability, <1:10 000
4 Low probability, <1:5 000
5 Low probability, <1:1 000
6 Medium probability <1:500
7 Medium probability, <1:100
8 High probability, <1:50
9 High probability, <1:10
10 Very high probability, 1:1

**S, Severity**
1 No effect
2 Limited effect on function or appearance
3 Limited effect on function or appearance
4 Severe effect on function or appearance
5 Minor reversible injury, no function
6 Minor reversible injury, no function
7 Severe reversible injury, small irreversible injury
8 Minor irreversible injury
9 Severe irreversible injury
10 Death

**Pd, Prob of detec.**
1 Will always be discovered
2 Very high probability of detection
3 High probability
4 Normal probability
5 Minor probability
6 Minor probability
7 Low probability
8 Low probability
9 Will probably not be detected
10 Will not be detected

PREVENTIA

# TVT-2

| | | |
|---|---|---|
| Reg No: MED-91 Reg | Artikel No: TVT-2 | Product: TVT-2 needles, introducer |
| Note: Treatment of SUI | Drawing No: P15113, P15111, P15112 | Dept: QA |
| Customer: | Responsible: ME / TS | Prepared: 1998-09-22 |
| Revision No: 7 | Revision date: 2000-02-06 | Page: 1 of 6 |

| Process step: | Failure mode | Cause | Effect | Control | Po | S | Pd | RPN | Action/follow-up | . | Responsi- | P- | S | P- | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (5) Preparing for the surgical procedure | Unsterile Introducer | Sterilisation (on site) has not been effective | Surgeons gloves unsterile -> risk for infection | Instruction from MMAB concerning cleaning and sterilisation | 1 | 6 | 2 | 12* | Acceptable risk | x | | 1 | 6 | 2 | 12* |
| | Unsterile TVT-2 device (single use) | Sterilisation process not effective | Infection | MMAB EN 46 001, sterilization validation performed | 1 | 8 | 2 | 16* | Acceptable risk | x | | 1 | 8 | 2 | 16* |
| | | Sterile package not effective | Infection | MMAB EN 46 001, sterile package validation performed | 1 | 8 | 2 | 16* | Acceptable risk | x | | 1 | 8 | 2 | 16* |
| | Damaged TVT-2 device | Unearefal handling during manufacture / transport / preparation | Tissue damage or new treatment | No pre-caution in instruction manual concerning damage during preparation. | 1 | 5 | 2 | 10* | Acceptable risk | x | | 1 | 5 | 2 | 10* |
| | | Needle falls outside the instrument table, tape stretched, protective sheath overlay separated | Tissue damage or new treatment | Normal preparation techniques in operating theater | 1 | 5 | 2 | 10* | Acceptable risk | x | | 1 | 5 | 2 | 10* |
| | | Protective caps falling off, needle tips damaged | Tissue damage or new treatment | The angle of the needle tip is same as 6 mm design. Protective caps. | 1 | 5 | 2 | 10* | Acceptable risk. | x | | 1 | 5 | 2 | 10* |
| | Wrong size of TVT device | Mislabelling of package / wrong shipment / wrong device prepared by nurse | The handle will not fit / treatment not possible | MMAB Quality system. 5 mm resp 6 mm needles have different article nos. | 1 | 4 | 1 | 4 | Acceptable risk | x | | 1 | 4 | 1 | 4 |

* = Risk of injury

PREVENTIA

# TVT-2

| | | |
|---|---|---|
| Reg No: MED-91 Eng | Artiel No: TVT-2 | Product: TVT-2 needles, introducer |
| Note: Treatment of SUI | Drawing No: P15113, P15111, P15112 | Dept: QA |
| Customer: | Responsible: ME / TB | Prepared: 1998-09-22 |
| Revision No: 7 | Revision date: 2008-02-06 | Page: 2 of 6 |

| Process step | Failure mode | Cause | Effect | Control | Fo | S | Fd | RPN | Action/follow-up | - | Responsi- | P- | S | P- | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (2) Attaching Introducer to the needle | Introducer loose from TVT-2 device | Screw not assembled correct in handle | Screw drops on the floor -> unsterile. New introducer must be prepared, delayed procedure. | Instr. for use describes procedure for introducer assembly after cleaning and sterilization | 1 | 5 | 1 | 5* | Acceptable risk | x | | 1 | 5 | 1 | 5* |
| | | 6 mm Introducer attached to 5 mm TVT-2 device needle | New Introducer must be prepared, delayed procedure | Not possible | 1 | 1 | 1 | 1 | Acceptable risk | x | | 1 | 1 | 1 | 1 |
| | | Screw threading on handle worn out | Screw drops on the floor -> unsterile. New Introducer must be prepared, delayed procedure | Assembly procedure in Instructions for use. Screw thread length increased. | 1 | 5 | 1 | 5* | Acceptable risk | x | | 1 | 5 | 1 | 5* |
| | Needle / Introducer attachment unstable | Screw not enough fixed | Unstable needle tip position, unintentional tissue damage (incl. Uretra). | | 1 | 8 | 1 | 8* | Acceptable risk. | x | | 1 | 8 | 1 | 8* |
| | | The screw slightly reversed (unwound) by the surgeons hand during procedure | Unstable needle tip position, unintentional tissue damage (incl. Uretra). | | 1 | 8 | 1 | 8* | Acceptable risk | x | | 1 | 8 | 1 | 8* |
| | Tape and protective sheath clamped between Introducer and Needle | Wrong assembly procedure by nurse / surgeon | Sheath separates. Damage to tissue due to damaged tape. New procedure required. | 1999-06-01: 20800 operations performed to date, no reports concerning this failure mode. | 2 | 5 | 2 | 20* | Acceptable risk. | x | ME | 2 | 5 | 2 | 20* |

* = Risk of injury

PREVENTIA

TVT-2

| | | |
|---|---|---|
| Reg No: MED-91 Eng | Artkl No: TVT-2 | Product: TVT-2 needles, introducer |
| Note: Treatment of SUI | Drawing No: P15113, P15111, P15112 | Dept: QA |
| Customer: | Responsible: ME / TS | Prepared: 1998-09-22 |
| Revision No: 7 | Revision date: 2000-02-06 | Page: 3 of 6 |

| Process step: | Failure mode | Cause | Effect | Control | Po | S | Pd | RPN | Action/follow-up | . | Responsi- | P- | S | P- | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Needle does not fit to introducer | Dimensions of Needle resp. Introducer wrong. | Needle not possible to fix to Introducer, Introducer sticks to Needle. New procedeure | Manufacturing of Needle validated | 1 | 4 | 1 | 4 | Acceptable risk. | x | | 1 | 4 | 1 | 4 |
| (3) Penetration of tissue / surface of abdomen | Penetration of bladder | Anatomy is such that it may happen | Patient catheter 1 / 3 days. | Cystoscope in bladder during procedure. Instruction available in surgical procedure | 8 | 5 | 2 | 80* | Acceptable risk. See litterature review. | | | 8 | 5 | 2 | 80* |
| | Penetration of Urethral wall | Damage by needle tip during insertion | Urethral wall damaged, leakage, scar on Urefkra | Instructions to use catheter guide. | 3 | 8 | 6 | 144* | Acceptable risk. | | | 3 | 8 | 6 | 144* |
| | Bleeding from pelvic floor / space of Rezius | Anatomy is such that it may happen | Bleeding in the tissue | Instructions for use, surgical procedure. Surgeon must be familiar with SUI procedure | 7 | 7 | 2 | 98* | Acceptable risk | | | 7 | 7 | 2 | 98* |
| | | TVT instrument unstable | Bleeding in the tissue | Instructions for use, surgical procedure. | 1 | 7 | 2 | 14* | Acceptable risk. | | | 1 | 7 | 2 | 14* |
| | Lateral vascular injury | Wrong surgical technique. | Bleeding in the tissue | Instructions for use, surgical procedure. Surgeon must be familiar with SUI procedure | 3 | 9 | 2 | 54* | Acceptable risk. Change instructions for use to include needle position in patient length direction | | | 3 | 9 | 2 | 54* |
| | | TVT instrument unstable | Bleeding in the tissue | Instructions for use, surgical procedure. | 1 | 9 | 2 | 18* | Postmarket surveillance. | | ME | 1 | 9 | 2 | 18* |
| | Damage to nerves, local anestesia | Anatomy is such that it may happen | Damage to nerve functions, pain | Instructions for use, surgical procedure | 2 | 8 | 2 | 32* | Acceptable risk | x | | 2 | 8 | 2 | 32* |

* = Risk of injury

PREVENTIA

# TVT-2

| | | |
|---|---|---|
| Reg No: MED-91 Eng | Artikl No: TVT-2 | Product: TVT-2 needles, introducer |
| Note: Treatment of SUI | Drawing No: P15113, P15111, P15112 | Dept: QA |
| Customer: | Responsible: ME / TS | Prepared: 1998-09-22 |
| Revision No: 7 | Revision date: 2009-02-06 | Page: 4 of 6 |

| Process step: | Failure mode | Cause | Effect | Control | Po | S | Pd | RPN | Action/follow-up | - | Responsi- | P- | S | P- | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Damage to nerves, spinal epidural general anestesia | Anatomy is such that it may happen | Damage to nerve functions, postoperative pain | No pain, more difficult | 2 | 8 | 6 | 96* | Acceptable risk | x | | 2 | 8 | 6 | 96* |
| | Bowl perforation / obstruction | Wrong surgical procedure, anathomy is such that it may happend | Pain, peritonitis | | 2 | 9 | 4 | 72* | Acceptable risk. | x | | 2 | 9 | 4 | 72* |
| | Needle torsion resistance too low | Diameter of needle 5 mm instead of 6 mm | Uncontrolled Needle tip position, unintentional tissue damage (incl Uretra). | Specification of tensile strength and torsion strength available in supplier certificate. | 1 | 8 | 2 | 16* | Acceptable risk. | x | | 1 | 8 | 2 | 16* |
| | Radius of Needle wrong | Wrong manufacturing | Uncontrolled Needle tip position. Unintentional tissue damage incl. Uretra | | 1 | 8 | 4 | 32* | Acceptable risk | x | ME | 1 | 8 | 4 | 32* |
| | Needle broken during procedure | Insufficient mechanical strength of Needle | Rests of the needle removed (surgical intervention). | | 6 | 5 | 1 | 30* | New needle design / material (2333) <2009-03-01 | | ME | 6 | 5 | 1 | 30* |
| | Protective sheath overlap separated | Wrong assembly | Damage to the prolene mesh, damage to tissue, new procedure | MMAB Quality system | 2 | 5 | 2 | 20* | Acceptable risk | x | | 2 | 5 | 2 | 20* |
| | | Accidental separation of overlap during surgical procedure | Damage to the prolene mesh, repeat the procedure | Surgeons attention | 2 | 5 | 2 | 20* | Acceptable risk | x | | 2 | 5 | 2 | 20* |
| | Needle resistance to tissue lower compared to 6 mm TVT sandblastered Needle | Smaller diameter compared to 6 mm | Less control of pos. of Needle tip during surg. procedure. | | 2 | 8 | 2 | 32* | Acceptable risk | x | ME | 2 | 8 | 2 | 32* |

* = Risk of injury

PREVENTIA

# TVT-2

| | | |
|---|---|---|
| Reg No: MED-91 Eng | Artel No: TVT-2 | Product: TVT-2 needles, introducer |
| Note: Treatment of SUI | Drawing No: P15113, P15111, P15112 | Dept: QA |
| Customer: | Responsible: ME / TS | Prepared: 1998-09-22 |
| Revision No: 7 | Revision date: 2000-02-06 | Page: 5 of 6 |

| Process step: | Failure mode | Cause | Effect | Control | Po | S | Pd | RPN | Action/follow-up | . | Responsi- | P- | S | P- | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Tape and protective sheath separates from Needle | Force of MT 5000 clear attachment (shrink tube) less compared to TVT generation I | New treatment, protective sheath remains in tissue, removed surgically | | 1 | 5 | 1 | 10* | Acceptable risk. | x | ME | 1 | 5 | 2 | 10* |
| | Toxicological reaction | Toxic material in clear attachment (shrink tube) Altera MT-5000 (clear) | Shock, sensibilization | Toxicological testing results of Raychem material available Altera MT-5000 (clear) | 1 | 8 | 2 | 16* | Acceptable risk | x | | 1 | 8 | 2 | 16* |
| | | Toxic material in protective sheath | Shock, sensibilization | Toxicological data available | 1 | 8 | 2 | 16* | Acceptable risk | x | | 1 | 8 | 2 | 16* |
| | | Toxic material in Prolene tape | Shock, sensibilization | Toxicological test results available | 1 | 8 | 2 | 16* | Acceptable risk | x | | 1 | 8 | 2 | 16* |
| (4) Removal and re-introduction of needle (in case of bladder penetration) | No risks identified. | | | | | | | | | | | | | | |
| (5) Release of Introducer from Needle | Needle does not separate from Introducer | Dimensions of Needle resp. Introducer wrong. | Excess force required to remove Needle. New procedeure. | Validation of manufacturing of Needles. | 2 | 4 | 2 | 16* | Acceptable risk. | x | | 2 | 4 | 2 | 16* |
| (6) Bringing the needle above the abdominal wall | Protective sheath loosens from mesh and/or mesh loosens before it is cut | Insufficient tensile strength below the protective sheath | Remove the protective sheath through surgical procedure. Repeat the procedure | | 2 | 6 | 2 | 24* | Acceptable risk. | x | | 2 | 6 | 2 | 24* |
| (7) Repeat on the other side | No specific risks identified | | | | | | | | | | | | | | |
| (8) Cutting tapes and remove needles | Tape and protective sheath slips below abdominal wall surface | Tape too short / woman too obese | Try to locate tape end, new procedure, alternative treatment | Instructions for use clear. | 2 | 4 | 2 | 16 | Acceptable risk | x | | 2 | 4 | 2 | 16 |

* = Risk of injury

PREVENTIA

# TVT-2

| | | | |
|---|---|---|---|
| Reg No: MED-91 Eng | Artikel No: TVT-2 | Product: TVT-2 needles, introducer | |
| Note: Treatment of SUI | Drawing No: P15113, P15111, P15112 | Dept: QA | |
| Customer: | Responsible: ME / TS | Prepared: 1998-09-22 | |
| Revision No: 7 | Revision date: 2000-02-06 | Page: 6 of 6 | |

| Process step: | Failure mode | Cause | Effect | Control | Po | S | Pd | RPN | Action/follow-up | - | Responsi- | P- | S | P- | RPN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (9) Tension adjustment and cough-test | Too hard tension | Wrong judgement by surgeon | Urine retention, residual urine, repeat the procedure, loosen the mesh | Instructions for use clear. | 2 | 5 | 2 | 20* | Acceptable risk. | x | | 2 | 5 | 2 | 20* |
| | Too loose tension | Wrong judgement by surgeon | No treatment effect (leakage). New procedure. | Instructions clear. | 2 | 5 | 2 | 20* | Acceptable risk | x | | 2 | 5 | 2 | 20* |
| (10) Removal of the protective sheath | Difficult to remove | Friction in overlap | Remove the protective sheath by other means, delay of procedure | | 3 | 5 | 1 | 15* | Acceptable risk | x | | 3 | 5 | 1 | 15* |
| | Particles from Prolene mesh falls off into the tissue | Tape edges damaged | No effect. Implantable material. | | 2 | 1 | 10 | 20 | Acceptable risk. | x | | 2 | 1 | 1-0 | 20 |
| (11) Cutting of the tape under the skin, suturing the incisions | No risks identified | | | | | | | | | | | | | | |
| (12) End of procedure | No risks identified | | | | | | | | | | | | | | |

* = Risk of injury

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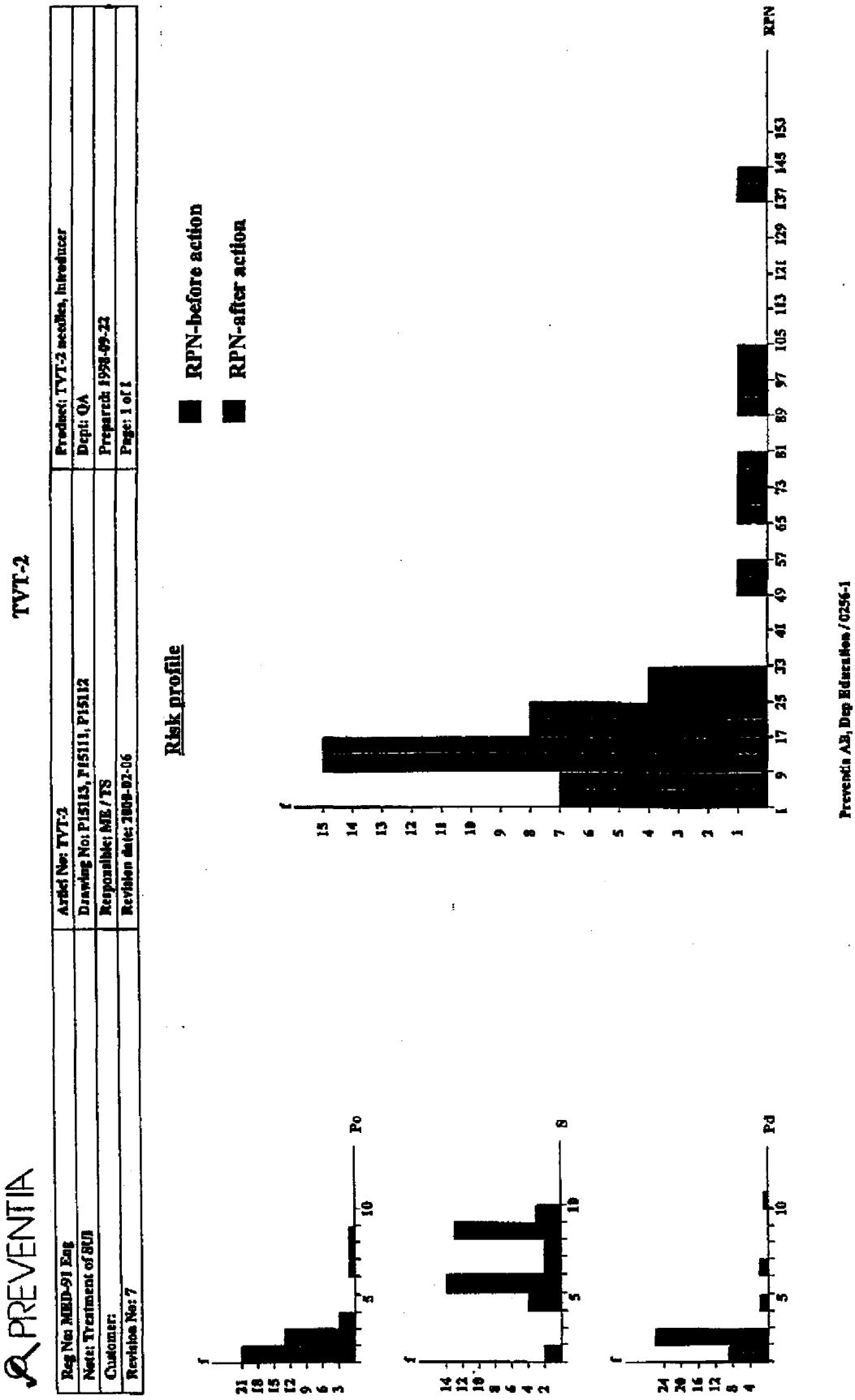
PREVENTIA
TVT-2
Reg No: MED-91 Eng
Note: Treatment of SUI
Customer:
Revision No: 7
Artikel No: TVT-2
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Prepared: 1998-09-22
Page: 1 of 1
Risk profile
RPN-before action
RPN-after action
RPN
Po
S
Pd
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